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## PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

INVENTOR(S)		Residence (City and either State or Foreign Country)			
Given Name (first and middle [if any]) Alex	Family Name or Surname BLIJEVSKY	Zichron Yaakov, ISRAEL			
<input type="checkbox"/> Additional inventors are being named on the ^ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (280 characters max)					
APPARATUS, SYSTEM AND METHOD TO INDICATE IN-VIVO DEVICE LOCATION					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input checked="" type="checkbox"/> Customer Number 27130		<input type="checkbox"/> Place Customer Number Bar Code Label here			
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<input checked="" type="checkbox"/> Firm or Individual Name Eitan, Pearl, Latzer & Cohen Zedek, LLP.					
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City	New York	State	New York	ZIP	10020
Country	USA	Telephone	212-632-3480	Fax	212-632-3489
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification Number of Pages 13 <input type="checkbox"/> CD(s), Number _____					
<input checked="" type="checkbox"/> Drawing(s) Number of Sheets 4 <input type="checkbox"/>					
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76 <input checked="" type="checkbox"/> Other (specify) postcard					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT (check one)					
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.					
<input type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 05-0649 FILING FEE AMOUNT (\$)					
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government. <input checked="" type="checkbox"/> No. <input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE

TYPED or PRINTED NAME: Caleb Pollack  
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Date 31 / Dec / 2003

REGISTRATION NO.  
(if appropriate)

37,912

Docket Number:

P-6259-USP

## USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Attorney Docket No. P-6259-USP

United States Provisional Patent Application For:

**APPARATUS, SYSTEM AND METHOD TO INDICATE IN-VIVO DEVICE  
LOCATION**

**FIELD OF THE INVENTION**

[0001] The present invention relates to in-vivo devices and methods for operating them. Specifically, embodiments of the present invention relate to systems, methods, and apparatuses that help in indicating in-vivo device location inside a body.

**BACKGROUND OF THE INVENTION**

[0002] Devices helpful in providing in-vivo imaging, diagnosis, treatments etc. are known in the art. For example, autonomous in-vivo devices, such as swallowable capsules, may move through a body lumen, collecting data as they move along. This data may be transmitted to an external reception device, and processed by a processing unit, to help, for example, determine in-vivo parameters. It would be highly advantageous to have a system or method to help indicate the location of an in-vivo device.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0003] The principles and operation of the system, apparatus, and method according to the present invention may be better understood with reference to the drawings, and the following description, it being understood that these drawings are given for illustrative purposes only and are not meant to be limiting, wherein:

[0004] Figure 1 is a schematic illustration of an in vivo device and imaging system according to one embodiment;

[0005] Figure 2 is a schematic illustration of an in vivo device according to some embodiments of the present invention; and

[0006] Figures 3A and 3B are flow charts illustrating methods for in-vivo location indication according to some embodiments of the present invention.

[0007] It will be appreciated that for simplicity and clarity of illustration, elements shown in the figures have not necessarily been drawn to scale. For example, the dimensions of some of the elements may be exaggerated relative to other elements for clarity. Further, where considered appropriate, reference numerals may be repeated among the figures to indicate corresponding or analogous elements throughout the serial views.

#### **DETAILED DESCRIPTION OF THE INVENTION**

[0008] The following description is presented to enable one of ordinary skill in the art to make and use the invention as provided in the context of a particular application and its requirements. Various modifications to the described embodiments will be apparent to those with skill in the art, and the general principles defined herein may be applied to other embodiments. Therefore, the present invention is not intended to be limited to the particular embodiments shown and described, but is to be accorded the widest scope consistent with the principles and novel features herein disclosed. In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be understood by those skilled in the art that the present invention may be practiced without these specific details. In other instances, well-known methods, procedures, and components have not been described in detail so as not to obscure the present invention.

[0009] Some embodiments of the present invention are directed to a typically swallowable in-vivo device that may be used for recording in vivo data, for example from the entire length of the gastrointestinal (GI) tract, and transmitting recorded data to a receiving and/or processing unit. Other embodiments need not be swallowable or autonomous, and may have other shapes or configurations. According to some embodiments the in vivo device may include an image sensor, however, other sensors may be used. Devices according to embodiments of the present invention may be

similar to or operate in a similar way to embodiments described in International Application WO 01/65995 and/or in US Patent Number 5,604,531, each of which are assigned to the common assignee of the present invention and each of which are hereby incorporated by reference in their entirety. Furthermore, receiving, storage, processing, and/or display systems suitable for use with embodiments of the present invention may be similar to embodiments described in WO 01/65995 and/or in US Patent Number 5,604,531. Of course, devices, systems, structures, functionalities, and methods as described herein may have other configurations, sets of components and processes etc.

[0010] Embodiments of the device are typically autonomous and are typically self-contained. For example, the device may be a capsule or other unit where all the components are substantially contained within a container or shell, and where the device does not require any wires or cables to, for example, receive power or transmit information. The device may communicate with an external receiving and display system to provide display of data, control, or other functions. For example, power may be provided by an internal battery or a wireless receiving system. Other embodiments may have other configurations and capabilities. For example, components may be distributed over multiple sites or units. Control information may be received from an external source.

[0011] Reference is now made to Fig. 1, which is a schematic illustration of an in-vivo imaging system 100, according to an embodiment of the invention. System 100 may include, for example, an in-vivo device 10, which may be, for example, a swallowable capsule. In-vivo device may include, for example, one or more detection units or detectors 30. In-vivo device may include, for example, one or more illumination units 43. System 100 may include a data reception unit 12 to receive at least in-vivo device data, and a data processor 14 to at least process at least in-vivo device data. System 100 may further include a displaying apparatus, such as a monitor 16, to display at least in-vivo device data. For example, data reception unit 12 may receive the data from in-vivo device 10, and may thereafter transfer the data to a data processor 14, and optionally a data storage unit 19. The data may be displayed on monitor 16. Data reception unit 12 may be separate from the processing unit 14 or combined with it. Data processor 14

may be, for example, associated with a personal computer or workstation, and may include, for example, a processor memory etc. Data processor 14 may be configured for real time processing and/or for post processing to be viewed or otherwise displayed at a later date. Units 14, 16 and 19 may be integrated into a single unit, for example a workstation 13, or any combinations of the various units may be implemented. Of course, other suitable components may be used. Device 10 may be an imaging device, or may include non-imaging capability.

[0012] Device 10 as depicted in Fig. 1 is capsule shaped, and may be easily swallowed and passively passed through the entire GI tract, pushed along, for example, by natural peristalsis. Nonetheless, it should be appreciated that device 10 may be of any shape and size suitable for being inserted into and passing through a body lumen or cavity, such as spherical, oval, cylindrical, etc. or other suitable shapes. Furthermore, device 10 or various embodiments that may include at least some components of device 10 may be attached or affixed on to an instrument that is inserted into body lumens and cavities, such as, for example, on an endoscope, laparoscope, stent, needle, catheter etc.

[0013] Reference is now made to Fig. 2, which is a schematic illustration of an in-vivo device, e.g., a swallowable capsule, according to an embodiment of the present invention, which may be adapted to indicate in-vivo device location within a body. Device 10 may include at least one illumination source 23, such as, for example, a white LED or any other suitable illumination source for illuminating a body lumen; an imager 24, such as, for example a CMOS imaging camera, a Charge Coupled Device (CCD), or any other suitable imaging device; and an optical system 22 including equipment, such as, for example, a lens, which may focus images onto imager 24. Illumination source 23 may illuminate the inner portions of a body lumen through at least one optical window 21. Device 10 may further include a transmitter 26 and an antenna 27 for transmitting signals and/or data received from at least imager 24, and a power source 25, such as, for example, a battery (e.g., a silver oxide battery, etc.) or any other suitable power source that may provide power to the electrical elements of device 10.

[0014] Device 10 may include a processor and/or controller 28, for example, an ASIC controller, optionally located within transmitter 26, or within any other component of device 10, to enable processing of recorded data and/or to control device 10.

Transmitter 26 may operate using radio waves, but in some embodiments, such as those where the device 10 is or is included within, for example, an endoscope, transmitter may transmit via, for example, a wire-based channel or another suitable method. In-vivo device 10 may include an imaging system for obtaining images from inside a body lumen, such as the GI tract, or may have no such imaging system. Other structures, components, and/or combinations of components may be used.

[0015] According to some embodiments of the present invention, device 10 may include one or more illumination detectors 30, which may be placed, for example, at one or more locations towards the outer shell of device 10 or at any other location of device 10, such that illumination generated by light sources 23 and reflected from in-vivo objects or lumen walls etc. to detector 30 is not received through optical window 21, for example, the device's "primary" optical window. For example, when the sides of device 10, in the vicinity of detector 30, are close to or touching the cavity or lumen walls (e.g., device 10 is passing through a relatively small, typically tube-like cavity), light emitted by illumination sources 23 may not substantially illuminate lumen walls or in-vivo objects in the area from which light may be reflected to detector 30. When the sides of device 10, in the region of detector 30, are not substantially close to the cavity or lumen walls (e.g., device 10 is passing through a relatively large cavity), light emitted by illumination sources 23 may illuminate lumen walls or in-vivo objects in the area from which light may be reflected to detector 30. In this way detector 30 may detect light from illumination sources 23 when device 10 is traversing a relatively large lumen, and may not detect substantial light from illumination source 23 when device 10 is traversing a relatively small lumen.

[0016] In one embodiment device 10 may include one or more illumination source(s) 43, which may be placed, for example, at one or more locations towards the outer shell of device 10. Illumination sources may be placed on the sides or at any other location of device 10, such that light generated by illumination source 43 and reflected from in-vivo objects or lumen walls etc. to detector 24 is not substantial when device 10 is passing through, for example, a narrow cavity.

[0017] In one embodiment device 10 may have one or more detectors 30 and one or more illumination sources 43. In an alternate embodiment other light sources, separate

from a primary light source (e.g., light sources 23), may operate via optical window 21, but may be configured to not be primary illumination sources. One or more detector(s), for example, imager 24, may be located in any suitable location in device 10 so as to receive illumination data from light sources 43 after being reflected off an in-vivo object or lumen wall etc. (and possibly passing through window 21). Imager 24, which may be used for other imaging functions for device 10, or may be wholly or partially dedicated to detection of illumination generated by light source(s) 43. For example, imager 24 may include a certain number of pixels in, for example, an unused or little used portion of an imager. Alternately, imager 24 may be placed closer to light sources 43, or to a path of light from light source(s) 43.

[0018] In some embodiments device 10 may have one or more optical windows 21, with associated imaging or other suitable components. Detector 30 may enable determination of ambient light in a lumen, resulting, for example, from the reflection of light from light sources 23 off a lumen wall. Detector 30 may be, for example, a CMOS camera, CCD, photodiode, or any other suitable light detector or imaging device. Detector 30 may be similar to imager 24, and in some embodiments detector 30 may replace imager 24. In further embodiments, an imager such as imager 24, may both provide in-vivo images and perform the functions of detector 30.

[0019] According to some embodiments of the present invention, when device 10 travels in-vivo through a relatively small diameter lumen, for example, such that the lumen walls are in close vicinity to the shell 20, which envelopes in-vivo device 10, and in close vicinity to detector 30, detector 30 may receive minimal or negligible reflected light or other electromagnetic information from light sources such as light source(s) 23 or 43. When device 10 travels through or into a relatively large diameter lumen (e.g., the stomach relative to the esophagus, the large intestine relative to the small intestine), or passes into or out of a relatively large space (e.g., into or out of the body itself) for example, such that a lumen wall is not necessarily in close vicinity to shell 20, light from light source 23 or 43 that reflects off the lumen walls (e.g., ambient light) may be wholly or partially received by detector 30.

[0020] According to some embodiments of the present invention, the movement of device 10 from a large space to a relatively small space may affect the amount of

electromagnetic energy recorded by detector 30. After not having received reflected light at detector 30 (or receiving a certain amount of light, or light below a threshold), when detector 30 receives light (or receives a different amount of light, or light above a predetermined threshold), for example, data from detector 30 may trigger transmission of a signal to indicate that device 10 is located within a substantially larger diameter lumen. Additionally or alternatively, when, for example, detector 30 that was receiving light stops receiving light or starts receiving substantially less light, data from detector 30 may trigger (for example via a separate controller or processor) transmission of a signal to indicate that device 10 is located within a substantially smaller diameter lumen.

[0021] In other embodiments, after detecting a status change in light received by detector 30, for example, after receiving substantially more light to detector 30, and/or receiving less or no light to detector 30, a controller (e.g., controller 28, transmitter 26 if it includes control or processing capability, or another suitable unit) may receive and process the data from detector 30, and may trigger one or more events to occur within device 10, by one or more components of device 10. Controller 28 may be the main processor/controller of in-vivo device 10 or it may be dedicated to detector 30 or other sub-systems. Another processing unit, such as transmitter 26, may be associated with detector 30. For example, controller 28 or another processing device may initiate sending of a signal and/or execution of an event in response to a status change in the light received by detector 30. In other embodiments, an imager such as imager 24 may collect light level data. For example, if moving from a relatively small diameter lumen into a larger diameter lumen affects the amount of light received by imager 24, such illumination changes may be used to indicate movement from one area to another.

[0022] In this way, detector 30 may enable provision of an indication as to an in-vivo device location in a body. For example, detector 30 or information received from detector 30, such as light level information, may indicate when device 10 has passed out of the small intestine (e.g., where the walls may be in close vicinity to device 10) and has moved into the large intestine, which has a larger diameter. Similarly, information from detector 30 may, for example, provide an indication as to when device 10, for

example, has passed out of the stomach and moved on to the small intestine, or has left the esophagus and moved into the stomach etc.

[0023] Examples of events that may be triggered following an indication by device 10 of a location change of device 10 may include, for example, commanding device 10 to transmit images after device 10 provides an indication that it has reached the colon; instructing device 10 to deliver medication or take samples etc. at one or more selected times and/or locations; instructing device 10 to start or finish events due to the indication given; instructing device 10 to change operation mode, etc. Other examples may include, for example, changing the focus of imager 24, changing the lighting from light sources 23 and/or 43, releasing a chemical, starting data transmission, shutting down or pausing imaging or other function, and initiating or ceasing in-vivo sensing by one or more sensing devices (e.g., pH sensor, temperature sensor, etc.). Other suitable mode changes or operations may take place. For example, device 10 may be controlled according to the location indication, thereby enabling energy saving for device 10, for example, by initiating events or ceasing events according to the progress of device 10 through the GI tract. Other events or operations may be triggered.

[0024] According to some embodiments of the present invention, detector 30 may transmit signals relating to light detection to controller 28, for example, ASIC controller, or any suitable data processing unit. Controller 28 may receive these signals and determine from the received signals, for example, by comparing the signals with prior received signals, whether or not there has been a status change in the light received by detector 30, for example, according to a pre-determined threshold. In the case where a status change in light received by detector 30 has been determined (e.g., substantially more light is received, or substantially less light is received), controller 28 may trigger a signal indicating, for example, a location change of device 10. The signal may be sent to any device 10 components, or may be transmitted to one or more receiving units outside device 10, by, for example, transmitter 26. Controller 28 may additionally or alternatively trigger an event, for example, in device 10, or in an external device such as, for example, data processor 14. Light status change may be determined according to the changes in quantity and/or quality of light received to detector 30. In an alternate embodiment data such as raw data or filtered data from detector 30 or another suitable

light detection component (e.g., an imager) may be transmitted to an external device (e.g., data processor 14), where a status change such as movement between different sized lumens may be determined. Such data may be transmitted, for example, via transmitter 26.

[0025] Reference is now made to Fig. 3A, which is a flow chart depicting a method for indicating in-vivo device location within a body, according to some embodiments of the present invention. An embodiment of the method, which may be, for example implemented using at least one light detector positioned such illumination reflected from the lumen walls to the detector is not substantially received through the device's primary optical window 21, for example, such that in a small diameter lumen, the detector will not receive light or will receive only light under a certain threshold. However, the method may be implemented using other in-vivo devices having other suitable structures. At block 300, a lumen may be illuminated using one or more light sources, for example, through an in-vivo device window. At block 305, the light reflected to one or more light detectors, for example positioned as described herein, may be detected.

[0026] At block 310, signals received from reflected light may be processed. At block 312 it may be determined whether there has been a change or substantial change in the quality and/or quality of light received by the detector. At block 315 if there is no substantial change in the quality and/or quality of light received, as determined according to a pre-determined threshold, the in-vivo device may continue functioning as before. At block 320, if there is a change in the quality and/or quality of light received, for example as determined according to a pre-determined threshold, the in-vivo device may send a signal to a reception unit, processing unit, and/or a user/operator etc. At block 325, if there is a change in the quantity and/or quality of light received, for example, as determined according to a pre-determined threshold, a user or operator of the in-vivo device may initiate and/or terminate one or more events. Additionally or alternatively, at block 330, if there is a change in the quantity and/or quality of light received, for example, as determined according to a pre-determined threshold, a user or operator of the in-vivo device may change a mode of operation. The initiating or terminating of events, and/or changing of operation mode etc. of the in-vivo device may

be implemented by a user or operator of the device, or by the device processor or alternative controller. Any combination of the above steps may be implemented. Further, other steps or series of steps may be used. For example, the steps of determining if a light pattern or level has changed to determine a position change may be performed by a processor external to the body based on signals transmitted from the in-vivo device.

[0027] According to another embodiment at block 312 it may be determined if the light being detected is above or below a predetermined threshold. According to this determination the device or components of the device may be made to continue operation (block 315) or to send a signal (block 320) or to initiate or terminate an event (block 325) or change a mode of operation (block 330) or any other suitable operation according to embodiments of the invention. The in-vivo device, for example, without the interaction of a user or operator, may implement these operations or other suitable operations. For example, an imaging device, such as described above, may be ingested, swallowed, or otherwise inserted by a patient. Upon swallowing, while the device is in the patient's esophagus and relatively little light (e.g., under a predetermined threshold) reaches the device's detector the imager of the device may be imaging at a high frame rate. When the imaging device reaches the patient's stomach a relatively large amount of light may be detected by a detector in the device and as a result the frame rate may be lowered. Various other mode changes may occur. When the device enters the small intestine from the stomach the amount of light detected by the detector may again be below a predetermined threshold and as a result the main illumination of the device may be intensified. Other steps and operations are possible.

[0028] Reference is now made to Fig. 3B, which is a flow chart depicting a method for indicating in-vivo device location within a body, according to some embodiments of the present invention. Embodiments of the method may be, for example implemented using at least one light source positioned on the sides of device 10 or at any other location of device 10, such that light discharged through light source(s) 43 which illuminates objects (for example, lumen walls), may not be reflected off the object or lumen wall and may not be detected by imager 24, when device 10 is traversing a small diameter

lumen. However, the method may be implemented using other in-vivo devices having other suitable structures.

[0029] At block 350, a lumen may be illuminated using one or more light sources, for example, at the sides of an in-vivo device or otherwise suitably positioned. At block 355, the light reflected off the in-vivo objects or lumen walls etc. to one or more light detectors, for example imager 24, may be detected. At block 360, signals received from reflected light may be processed, for example, by processor 28 or other suitable processing units. At block 365, if there is no substantial change in the quality and/or quality of light received, as determined according to a pre-determined threshold, the in-vivo device and/or an external processing or receiving system may continue functioning as before. At block 370, if there is a change in the quality and/or quality of light received, for example as determined according to a pre-determined threshold, a user or operator of the in-vivo device may send a signal to a reception unit, processing unit, and/or a user/operator etc. In the case where a user and/or operator receive a signal or data, the user and/or operator may provide an instruction to initiate or terminate an event in the in-vivo device or in other system components.

[0030] At block 375, if there is a change in the quantity and/or quality of light received, for example, as determined according to a pre-determined threshold, a user or operator of the in-vivo device may initiate and/or terminate one or more events. Additionally or alternatively, at block 380, if there is a change in the quantity and/or quality of light received, for example, as determined according to a pre-determined threshold, a user or operator of the in-vivo device may change a mode of operation of the device and/or an external system. The initiating or terminating of events, and/or changing of operation mode etc. of the in-vivo device may be implemented by a user or operator of the device, or by the device processor or alternative controller. Any combination of the above steps may be implemented. Further, other steps or series of steps may be used. For example, the steps of determining if a light pattern or level has changed to determine a position change may be performed by a processor external to the body based on signals transmitted from the in-vivo device.

[0031] According to another embodiment at block 362 it may be determined if the light being detected is above or below a predetermined threshold. According to this

determination the device may be made to continue operation (block 365) or to send a signal (block 370) or to initiate or terminate an event (blocks 375 and 380 respectively) or any other operation according to embodiments of the invention. The in-vivo device, for example, without the interaction of a user or operator, may implement these operations or other suitable operations.

[0032] According to some embodiments of the present invention, the in-vivo motion detection may be implemented using at least one light detector 30 and at least one light source 43; both being positioned substantially separately from the main illumination and light detection units (23 and 24 respectively) of in-vivo device 10. For example, the detection unit(s) may be placed so as to detect light that is substantially reflected from an in-vivo object or lumen wall etc., the light having emanated from light source 43. For example, the illumination unit(s) may be placed so as to generate light that substantially illuminates an in-vivo object or lumen wall etc. not using optical window 21 (e.g., detector may be located on one or more sides of in-vivo device 10). In this way, for example, in a small diameter lumen, the detector may not receive light or may only receive light under a certain threshold, while in a large lumen, the detector may receive light above a certain threshold.

[0033] The foregoing description of the embodiments of the invention has been presented for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. It should be appreciated by persons skilled in the art that many modifications, variations, substitutions, changes, and equivalents are possible in light of the above teaching. It is, therefore, to be understood that the appended claims are intended to cover all such modifications and changes as fall within the true spirit of the invention.

**CLAIMS**

What is claimed is:

1. A system as described in the specification and drawings.
2. A method as described in the specification and drawings.

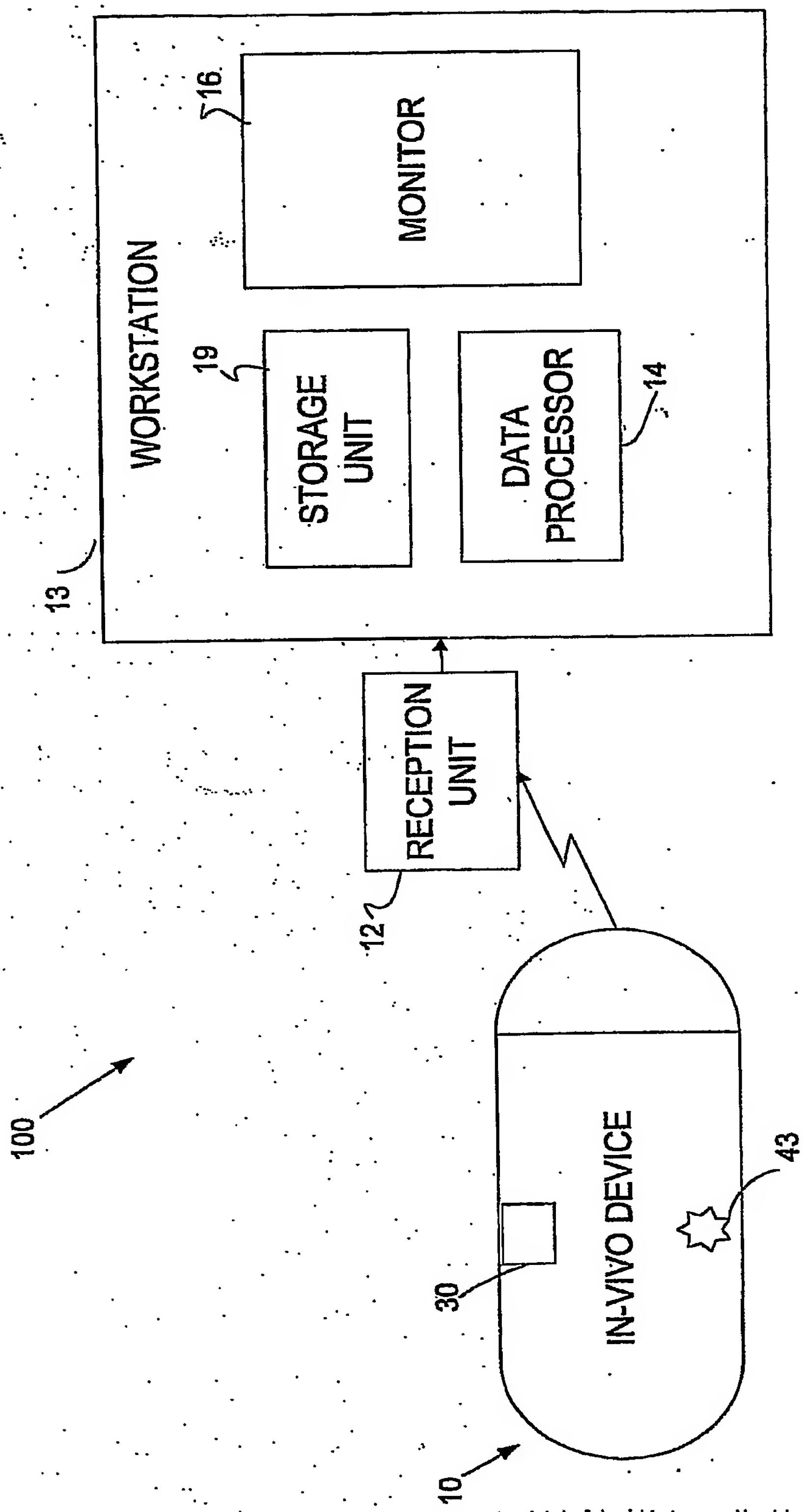


FIG. 1

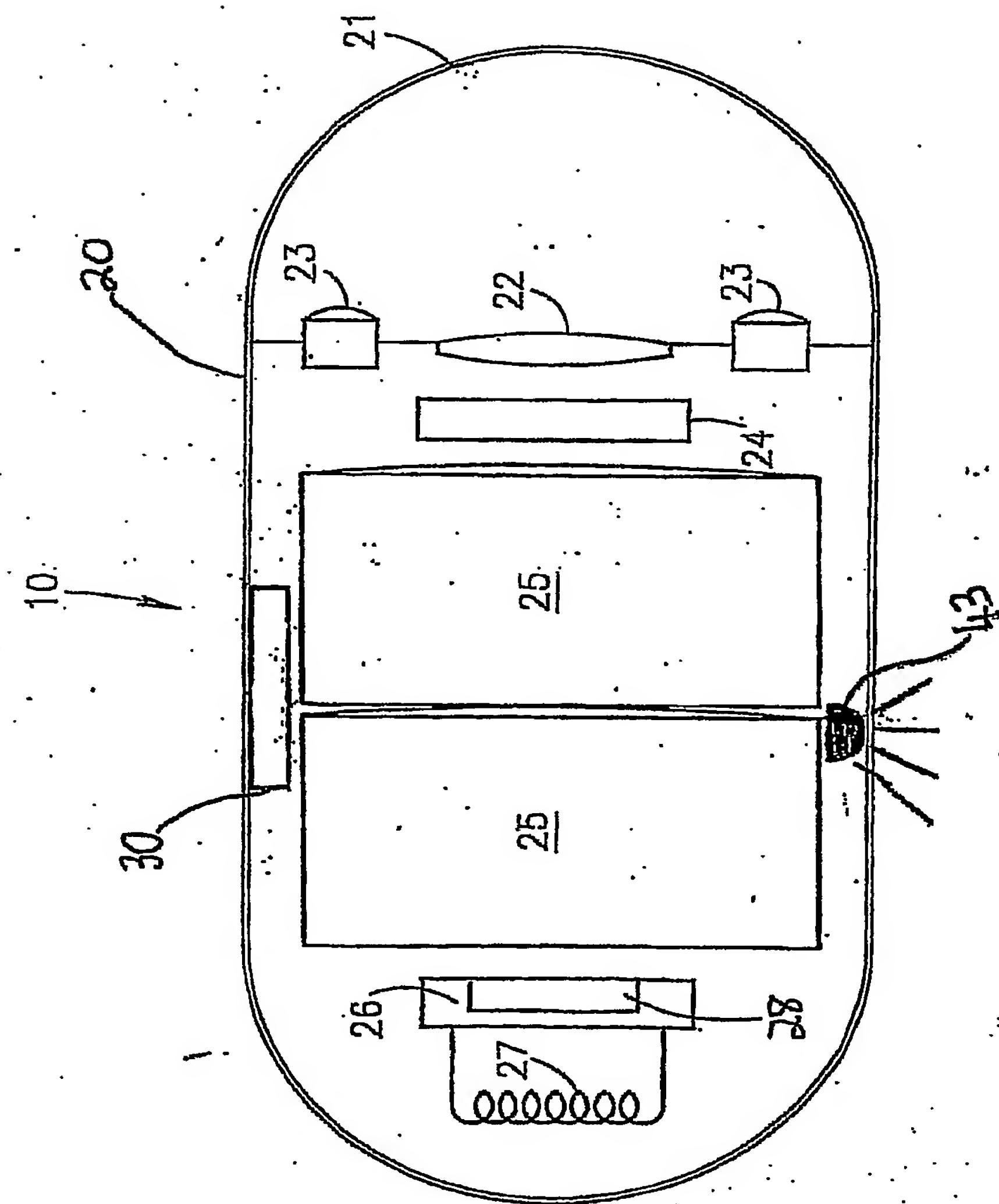


FIG. 2

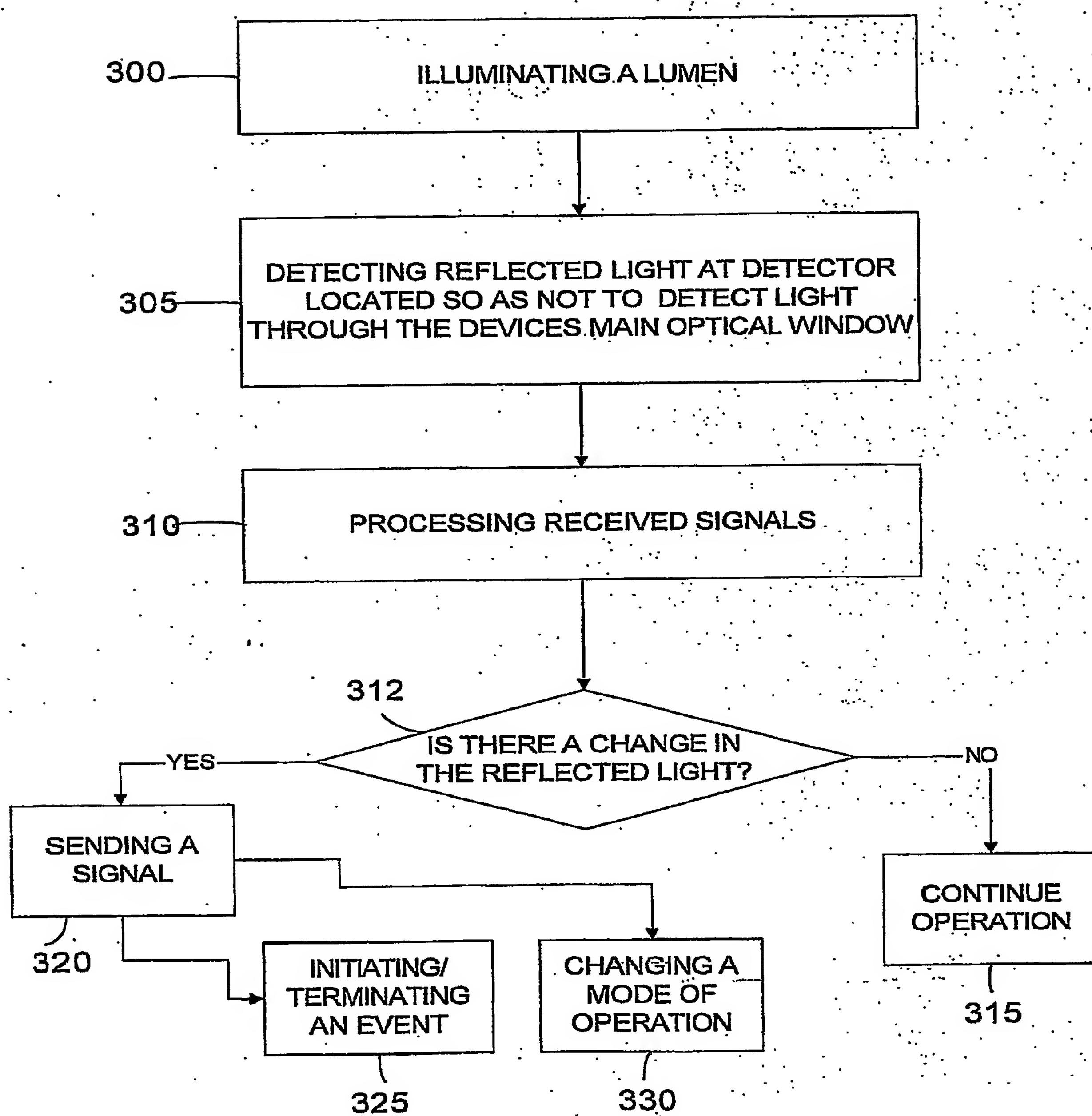


FIG. 3A

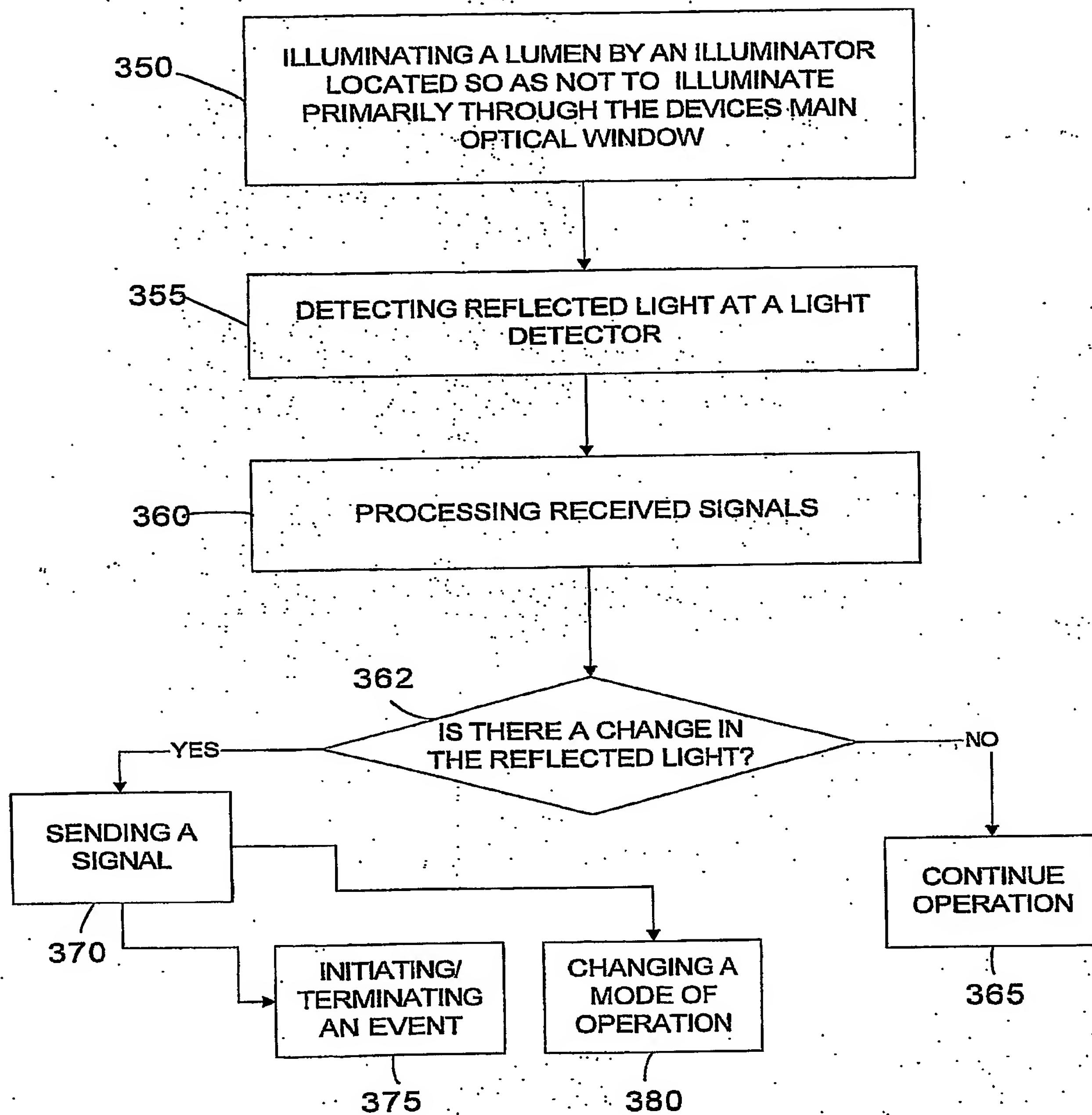


FIG. 3B